Assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011)

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Assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011)

EFSA Panel on Genetically Modified Organisms (GMO),
Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins, Fabien Nogué, Nils Rostoks, Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann, Fabio Veronesi, Fernando Álvarez, Michele Ardizzone and Konstantinos Paraskevopoulos

Abstract

Following the submission of application EFSA-GMO-RX-011 under Regulation (EC) No 1829/2003 from Monsanto Europe, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified soybean MON 89788, for food and feed uses, excluding cultivation within the European Union. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequence of the event in soybean MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788.

Keywords: Soybean, MON 89788, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2017-00826

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Summary

Following the submission of application EFSA-GMO-RX–011 under Regulation (EC) No 1829/2003[1] from Monsanto Europe S.A., the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified (GM) soybean MON 89788. The scope of the renewal application EFSA-GMO-RX-011 is for placing on the market of products containing, consisting of, or produced from soybean MON 89788, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-011, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-011 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses and additional studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the event in soybean MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788 (EFSA, 2008).

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

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1. Introduction

1.1. Background

On 7 December 2017, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-011 by Monsanto Europe S.A. for the renewal of authorisation of genetically modified (GM) soybean MON 89788 (Unique Identifier MON-89788-1) for the placing on the market of products containing, consisting of, or produced from this GM soybean submitted within the framework of Regulation (EC) No 1829/2003. Before sending the application to EFSA, the European Commission confirmed whether the data submitted in the context of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving application EFSA-GMO-RX–011, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the European Union (EU) Member States and made the summary of the application available to the public on the EFSA website.[2]

On 9 April 2018, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had 3 months after the opening of the Member State commenting period (until 9 July 2018) to make their opinion known.

Following the submission of application EFSA-GMO-NL-2006-36 and the publication of the EFSA scientific opinion (EFSA, 2008), the placing on the market of soybean MON 89788 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Decision 2008/933/EC[3]. A copy of this authorisation was provided by the applicant.[4]

EFSA requested additional information on 27 July 2018. The applicant submitted its reply on 6 August 2018.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of 6 months from the acknowledgement of the valid application. As additional information was requested by the GMO Panel, the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the placing on the market of products containing, consisting of, or produced from GM soybean MON 89788, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of genetically modified organisms (GMOs) or food and feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food and feed and/or food and feed produced from it), which are matters related to risk management.

[2] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2017-00826

[3] COMMISSION DECISION of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2008/933/EC). Official Journal of the European Union L 333/7, 11.12.2008.

[4] Dossier: Soybean MON 89788 renewal – Annex 1.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-011 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the context of this renewal application, no new sequencing study was submitted among the additional documents or studies performed by or on behalf of the applicant. In accordance with the GMO Panel guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015a), the GMO Panel evaluated the data provided in the context of this soybean MON 89788 renewal application under the assumption that the MON 89788 event sequence is identical to the sequence of the originally assessed event (EFSA, 2008).

2.1.1. Post-market monitoring reports[5]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from soybean MON 89788, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of soybean MON 89788 (EFSA, 2008), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from December 2008 to July 2017. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in soybean seeds import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean possibly containing soybean MON 89788; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[6]

In addition to the nine separate literature searches provided as part of the annual PMEM reports, two systematic literature searches[7] for soybean MON 89788 and the newly expressed CP4 EPSPS protein, covering the period from 1 January 2007 until 31 July 2018, were performed by the applicant in accordance with the recommendations on literature searching outlined in EFSA (2010, 2017a).

Searches against two electronic bibliographic databases and internet searches to specialist databases were performed to identify relevant publications. Altogether, 845 publications were retrieved.[8] After applying the eligibility/inclusion criteria defined *a priori* by the applicant, seven publications were identified as relevant for food and feed safety assessment, molecular characterisation and environmental safety assessment. The list of relevant publications is provided in Appendix A.

2.1.3. Updated bioinformatic data[9]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for soybean MON 89788 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, and an analysis of possible horizontal gene transfer performed as described in EFSA (2017b). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

[5] Dossier: Soybean MON 89788 renewal – Annex 2.
[6] Dossier: Soybean MON 89788 renewal – Annex 3.1; additional information: 6/8/2018.
[7] An initial search provided in Annex 3.1 of the dossier, covering from 1/1/2017 to 4/8/2117, and an updated search provided on 6/8/2018, covering the period from 1/1/2017 to 31/7/2018.
[8] Seven hundred and fifty-nine publications were retrieved in the initial search (reporting period: 1/1/2007–4/8/2017) and 86 publications were retrieved in the updated search (reporting period: 1/1/2017–31/7/2018).
[9] Dossier: Soybean MON 89788 renewal – Annex 3.2.

2.1.4. Additional documents or studies provided by the applicant[10]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015a), the applicant provided an overview on the worldwide approvals of soybean MON 89788 and the full reports of all studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU (Appendix B).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant.

2.1.5. Overall assessment as provided by the applicant[11]

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015a), the applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean MON 89788 for food and feed use and processing in the EU, does not change the outcome of the original risk assessment (EFSA, 2008).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[12]

The applicant indicated in the dossier that the environmental monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the application for the renewal of authorisation of soybean MON 89788 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015a).

The comments raised by Member States are addressed in Annex G of EFSA's overall opinion[13] and were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of soybean MON 89788, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on soybean MON 89788. Although the overall quality of the performed literature searches is acceptable, the GMO Panel considers that future searches could be improved. The GMO Panel therefore recommends the applicant for future searches to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues);
- use truncation consistently;
- include controlled vocabulary (subject indexing) in the searches when available, and where subject headings are available, use both free-text terms and controlled vocabulary in the searches.

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on soybean MON 89788 (EFSA, 2008) have been identified by the applicant.

[10] Dossier: Soybean MON 89788 renewal – Annex 3.3.
[11] Dossier: Soybean MON 89788 renewal – Page 3.
[12] Dossier: Soybean MON 89788 renewal – Annex 4.
[13] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00812

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of soybean MON 89788 confirm that no known endogenous genes were disrupted by the insert. Analyses of the amino acid sequence of the newly expressed CP4 EPSPS protein reveal no significant similarities to toxins or allergens. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA reveal no significant similarities to toxins and allergens.

The updated bioinformatic analyses confirm the previous conclusions on the likelihood of occurrence of horizontal gene transfer for soybean MON 89788 event (EFSA GMO Panel, 2015b). It was concluded that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from soybean MON 89788 to bacteria did not raise any environmental safety concern.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the full study reports of the additional studies provided (Appendix B). This new information does not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on soybean MON 89788.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA-GMO-RX-011 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean MON 89788.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM soybean plant material, including soybean MON 89788. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in soybean seeds import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of soybean MON 89788 but reminds that monitoring is related to risk management, and thus the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

Under the assumption that the DNA sequence of the event in soybean MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788 (EFSA, 2008).

Documentation provided to EFSA

1) Letter from the European Commission to EFSA received on 7 December 2017 for the continued marketing of genetically modified soybean MON 89788 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Monsanto Europe (EFSA-GMO-RX-011).
2) Acknowledgement letter, dated 19 December 2017, from EFSA to the European Commission.
3) Letter from EFSA to applicant dated 8 February 2018 requesting additional information under completeness check.
4) Letter from applicant to EFSA received on 14 March 2018 providing additional information under completeness check.
5) Letter from EFSA to applicant dated 9 April 2018 delivering the 'Statement of Validity' for application EFSA-GMO-RX-011.
6) Letter from EFSA to applicant dated 27 July 2018 requesting additional information and stopping the clock.
7) Letter from applicant to EFSA received on 6 August 2018 providing additional information.
8) Letter from EFSA to applicant dated 6 August 2018 re-starting the clock from 6 August 2018.

References

EFSA (European Food Safety Authority), 2008. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2006-36) for the placing on the market of the glyphosate-tolerant genetically modified soybean MON 89788, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2008;6(7):429, 23 pp. https://doi.org/10.2903/j.efsa.2008.758

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015a. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. https://doi.org/10.2903/j.efsa.2015.4129

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015b. Scientific Opinion on an application (Reference EFSA-GMO-NL-2011-100) for the placing on the market of the herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2015;13(7):4178, 30 pp. https://doi.org/10.2903/j.efsa.2015.4178

EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Glanville J and Waigmann E, 2017a. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2017;14(4):EN-1207, 48 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1207

EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogue F, Papadopoulou N and Tebbe C, 2017b. Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA supporting publication 2017;14(7):EN-1273, 11 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1273

Abbreviations

ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
GMO	Panel EFSA Panel on Genetically Modified Organisms
ORFs	open reading frames
PMEM	post-market environmental monitoring

Appendix A – List of relevant publications identified by the applicant through the systematic literature search

Reference
Berman KH, Harrigan GG, Riordan SG, Nemeth MA, Hanson C, Smith M, Sorbet R, Zhu E and Ridley WP, 2010. Compositions of forage and seed from second-generation glyphosate-tolerant soybean MON 89788 and insect-protected soybean MON 87701 from Brazil are equivalent to those of conventional soybean (*Glycine max*). Journal of Agricultural and Food Chemistry, 58, 6270–6276.
Harrigan GG, Glenn KC and Ridley WP, 2010. Assessing the natural variability in crop composition. Regulatory Toxicology and Pharmacology, 58, S1–S20.
Horak MJ, Rosenbaum EW, Kendrick DL, Sammons B, Phillips SL, Nickson TE, Dobert RC, Perez T, 2015. Plant characterization of Roundup Ready 2 Yield® soybean, MON 89788, for use in ecological risk assessment. Transgenic Research, 24, 213–225.
Lundry DR, Ridley WP, Meyer JJ, Riordan SG, Nemeth MA, Trujillo WA, Breeze ML and Sorbet R, 2008. Composition of grain, forage, and processed fractions from second-generation glyphosate-tolerant soybean, MON 89788, is equivalent to that of conventional soybean (*Glycine max* L.). Journal of Agricultural and Food Chemistry, 56, 4611–4622.
Taylor M, Hartnell G, Lucas D, Davis S and Nemeth M, 2007. Comparison of broiler performance and carcass parameters when fed diets containing soybean meal produced from glyphosate-tolerant (MON 89788), control, or conventional reference soybeans. Poultry Science, 2608–2614.
Vries BDD and Fehr WR, 2011. Impact of the MON89788 event for glyphosate tolerance on agronomic and seed traits of soybean. Crop Science, 51, 1023–1027.
Zhou J, Berman KH, Breeze ML, Nemeth MA, Oliveira WS, Braga DPV, Berger GV and Harrigan GG, 2011. Compositional variability in conventional and glyphosate-tolerant soybean (*Glycine max* L.). varieties grown in different regions in Brazil. Journal of Agricultural and Food Chemistry, 59, 11652–11656.

Appendix B – List of additional studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU with regard to the evaluation of the safety of the food and feed for humans, animal or the environment from soybean MON 89788

Study identification	Title
MSL0020867	Phenotypic evaluation and ecological interactions of MON 89788 glyphosate tolerant soybean in U.S. field trials during 2006
MSL #21149	Composition analyses of MON 89788 soybean untreated and treated with Roundup® herbicide grown in the United States in 2007
MSL #21238	Compositional analyses of MON 89788 soybean seed and forage untreated and treated with Roundup herbicide grown in Puerto Rico in 2007
MSL0022100	Amended report for MSL0021786: Compositional analyses of soybean forage and Harvested Seed Collected from MON 89788 grown in Brazil field trials during 2007/2008
MSL0022336	Amended report for MSL0021981: Compositional analyses of soybean seed collected from MON 89788 untreated with glyphosate grown in Brazil during 2007/2008
MSL0023111	Amended report for MSL0022443: Compositional analyses of soybean forage and seed collected from MON 89788 (glyphosate-treated) grown in Brazil during 2008/2009
MSL0023114	Amended report for MSL0022446: Compositional analyses of soybean forage and seed collected from MON 89788 (untreated) grown in Brazil during 2008/2009
MSL0023106	Compositional analyses of soybean forage and seed collected from MON 89788 grown in the United States during the 2009 growing season
MSL0023745	PCR analysis to confirm the absence of *Agrobacterium tumefaciens* used to produce MON 89788
MSL0023945	Amended report for MSL0023050: Phenotypic evaluation and environmental interactions of glyphosate-tolerant soybean MON 89788 when sprayed with glyphosate in U.S. field trials during 2009
MSL0024759	Amended report for MSL0022764: Immunodetection of CP4 EPSPS following heat treatment